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62281

November 11, 1998

Via Certified Mail. Return Receipt Requested

Office of Special Nutritionals **HFS 450** Center for Food Safety and Applied Nutrition Food and Drug Administration 200 C. Street, S.W. Washington, D.C. 20204

Notification Letter for Statements of Nutritional Support

Dear Sir or Madam:

Our firm has been authorized by Catalysis, S.L. to represent it in all of its activities with the Food and Drug Administration including, but not limited to, filing its notification letters for statements of nutritional support.

Enclosed for your review and approval are notification letters executed by Catalysis, S.L. for its dietary supplements "VIUSID" and "KALSIS" which it intends to introduce in to the market in the coming months.

Thank you for your assistance on this matter. If you have any questions concerning the notification letters, please do not hesitate to contact me at (305) 536-6270.

Respectfully submitted,

Poll & Guesada

Pablo S. Quesada, Esq.

Enclosures



Zurbano, 39 28010 Madrid / Spain P. O. Box 19004 28028 Madrid / Spain

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OFFICE OF SPECIAL NUTRITIONALS HFS 450 CENTER FOR FOOD SAFETY AND APPLIED NUTRITION 200 C. STREET, S.W. WASHINGTON, D.C. 20204 ESTADOS UNIDOS

Madrid, October 6, 1998

Re: Notification Letter for Statements of Nutritional Support

Dear Sir or Madam:

1.- <u>Statement of Purpose</u>. This notification letter is to provide notification of the following statements of nutritional support "VIUSID is a nutritional preparation specially designed for the increase of the immunilogical defenses in all those processes that cause immonodeficiency".

2.- Vendor Information. Manufacturer:

CATALYSIS, S.L.

Addres:

C/ Zurbano, 39

28010 Madrid, Spain

Telephone:

+34 1 345 69 02

3.- Product identification. Trade name: VIUSID

VIUSID is a dietary supplement made out of honey. The activation of the components of VIUSID increases to a great extent the power of the biological function of all of them, without mofifying or changing the molecular structure.

- 4.- <u>Ingredient Statement.</u> Honey, Maleic Acid, Arginine, Glucosamine, Glycine, Ascorbic Acid, Pyridoxal, Folic Acid, Calcium Pantotenate, Zinc Sulfate, Cyanocobalamin, Lemon, Mint, Sodium Methylparaben, Sunett, Aspartame and Water.
- 5.- <u>Intended Use.</u> VIUSID is presented in flasks of 100 ml. The recommended dosage is one flask daily for adults and half a flask daily for children, taken in several doses during the day. The time of consumption can be prolonged according to the cases, since no contraindications have been detected.
- 6.- <u>Statements of Affirmation</u>. The information contained in this notice is complete and accurate and there is supporting evidence that the statement of nutritional support is truthful, nor misleading and scientifically valid. Moreover, the product does not present a significant or unreasonable risk of illness or injury under the conditions of use recommended or suggested in the labeling.

Respectfully submitted,

CATALYSIS, S.L.

<del>JOSE</del>TTE DECAUX GENERAL MANAGER

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OFFICE OF SPECIAL NUTRITIONALS HFS 450 CENTER FOR FOOD SAFETY AND APPLIED NUTRITION 200 C. STREET, S.W. WASHINGTON, D.C. 20204 ESTADOS UNIDOS

Madrid, October 6, 1998

Re: Notification Letter for Statements of Nutritional Support

Dear Sir or Madam:

1.- <u>Statement of Purpose</u>. This notification letter is to provide notification of the following statements of nutritional support "KALSIS is specially designed to help strengthen the bone structure" and "KALSIS is a new nutritional complex specially formulated to improve and accelerate the reconstruction of the bone structure".

2.- Vendor Information, Manufacturer:

CATALYSIS, S.L.

Addres:

C/ Zurbano, 39

28010 Madrid, Spain

Telephone:

+34 1 345 69 02

3.- Product identification. Trade name: KALSIS

KALSIS is a dietary supplement made of Lactobacillus rootstocks, which, when combined with Selenium, increase and accelerate the deposit of Calcium on the bones.

- 4.- <u>Ingredient Statement.</u> Lactobacillus Acidophilus and Casei 25%, Organic Selenium, Calcium Gluconate, Magnesium Gluconate, Vitamin C, Vitamin E, Citric Fiber, Oats Bran and Milk Serum.
- 5.- <u>Intended Use.</u> The recommended dosage is one capsule before the three main meals of each day.
- 6.- Statements of Affirmation. The information contained in this notice is complete and accurate and there is supporting evidence that the statement of nutritional support is truthful, nor misleading and scientifically valid. Moreover, the product does not present a significant or unreasonable risk of illness or injury under the conditions of use recommended or suggested in the labeling.

Respectfully submitted, CATALYS!S, S.L.

JOSETTE DECAUX GENERAL MANAGER

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